For Consumers

FDA's MedWatch Safety Alerts: July 2010

[1]

Get Consumer Updates by E-mail[2]

Consumer Updates RSS Feed[3]

On this page:

After the Food and Drug Administration (FDA) approves a product and it is on the market, the agency continues to monitor that product for unexpected and undesirable side effects (adverse events).

Health care professionals and consumers may report side effects, product quality problems, product use errors, or therapeutic failure when using medical products to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, by fax, or by phone.

- Online[4]
- Regular Mail: Use postage-paid, pre-addressed FDA form 3500[5]
- Fax: 1-800-FDA-0178
- Phone: 1-800-332-1088

MedWatch reports can signal a safety problem and lead to FDA action to protect the public from harm, serious illness, or death.

Here are some of the most recent safety alerts prompted by reports FDA has received from health care professionals and patients.

Miracle Mineral Solution: Dangerous to Drink

Miracle Mineral Solution, also known as "Miracle Mineral Supplement" or "MMS," should not be consumed.

MMS is distributed on Internet sites and online auctions. MMS claims to treat HIV, hepatitis, the H1N1 flu, common colds, acne, cancer, and other conditions. FDA is not aware of any research showing that MMS is effective in treating any of these conditions.

The risk: When mixed with citrus juice or other acid as directed, the mixture produces a bleach used for stripping textiles and industrial water treatment. High doses of this bleach—such as those recommended on the label—can cause nausea, vomiting, diarrhea, and severe dehydration.

Recommendations

- Stop using MMS immediately and throw it away.
- If you have experienced any bad side effects from MMS, contact your health care professional immediately.

back to top

Evamist: Keep Children and Pets Away

Children and pets should not come in contact with Evamist on the skin. Evamist is a drug for women that is sprayed on the inside of the forearm between the elbow and wrist to reduce hot flashes during menopause.

The risk: FDA has received reports of side effects in children who were unintentionally exposed to Evamist. Side effects include

- nipple swelling and breast development in girls
- breast enlargement in boys

FDA has also received reports of unintentional exposure in pets, which may show signs of mammary/nipple enlargement and vulvar swelling.

Recommendations

- Do not allow children to come in contact with the area of the arm where Evamist was sprayed.
- If a child is exposed to Evamist, wash the child's skin with soap and water as soon as possible. Contact the child's healtl care professional if nipple or breast swelling or breast tenderness occur in girls, or breast enlargement occurs in boys.
- Do not allow pets to lick or touch the arm where Evamist was sprayed. Small pets may be especially sensitive to Evamist. Contact a veterinarian if your pet shows any sign of illness, including enlargement of the nipples or vulva.
- Women who use Evamist should wear clothing that covers the arm sprayed with the drug if they cannot prevent accidental contact.

For More Information

Consumer Update: Keep Kids, Pets Away From Skin Sprayed With Evamist[6]

Drug Safety Communication on Evamist[7]

back to top

Advair Diskus: Stolen Inhalers Pose Risk

Advair Diskus inhalers stolen from a Virginia warehouse have shown up in some pharmacies.

Advair Diskus (fluticasone propionate and salmeterol inhalation powder) is an inhaler used to treat people with asthma or chronic obstructive pulmonary disease.

The risk: The safety and effectiveness of stolen inhalers cannot be assured. The inhalers may have been stored at improper temperatures or humidity levels—or they might have been contaminated or lost potency.

The stolen Advair Diskus inhalers are

- Lot 9ZP2255 - NDC 0173-0696-00, Advair Diskus 250/50, 60 Dose, Exp: Sep 2010
- Lot 9ZP3325 - NDC 0173-0697-00, Advair Diskus 500/50, 60 Dose, Exp: Sep 2010

Recommendations

- If you have an inhaler with either of the lot numbers listed above, stop using it immediately and contact GlaxoSmithKline's Customer Response Center at 888-825-5249.
- Contact your physician or pharmacist to obtain a proper replacement.
- Report suspicious or unsolicited offers for the Advair Diskus lots in question by contacting FDA's Office of Criminal Investigations[8].

For More Information

Consumer Update: Stolen Inhalers Pose Risk[9]

back to top

Qualaquin: Risk of Serious Reactions

People who use the drug Qualaquin to treat or prevent nighttime leg cramps may be at risk for serious and life-threatening reactions.

Qualaquin (quinine sulfate) is FDA-approved only for treatment of a certain type of malaria. However, most of Qualaquin's use in the U.S. is to treat or prevent nighttime leg cramps—a use not approved by FDA.

The risk: People who have used Qualaquin to prevent or treat leg cramps or restless leg syndrome have reported side effects including severe lowering of platelets in the blood. Permanent kidney damage, hospitalization, and two deaths have resulted from some of these blood-related side effects.

Recommendations

- If you take Qualaquin for nighttime leg cramps, discuss other treatment options with your health care professional.
- Contact your health care professional immediately if you bruise easily; have severe nose bleeds, blood in your urine or stool, or bleeding gums; or if unusual purple, brown, or red spots appear on your skin.
- Read the medication guide given to you at the pharmacy when you pick up a prescription for Qualaquin.

For More Information

Consumer Update: Using Malaria Medication for Leg Cramps is Risky[10]

FDA Drug Safety Communication[11]

back to top

Arava: Risk of Severe Liver Injury

FDA is requiring a "boxed warning" on the label of the rheumatoid arthritis drug Arava to highlight the risk of severe liver injury.

A boxed warning appears prominently at the top of a drug label and is required for certain prescription drugs. The warning calls attention to serious or life-threatening risks.

The risk: FDA has received reports of severe liver injury, including death from liver failure. The greatest risk for liver injury was seen in patients taking other drugs known to cause liver injury, and patients with pre-existing liver disease.

Recommendations

- Be aware that severe liver injury is a rare, but serious, side effect of Arava.
- Contact your health care professional right away if you develop itching, yellow eyes or skin, dark urine, loss of appetite, or light-colored stools. These may be signs of liver injury.
- Talk to your health care professional about any concerns you have with this medication.

For More Information

FDA Drug Safety Communication[12]

back to top

Que She Herbal Supplement: Unapproved Drug

Que She, marketed as an herbal weight-loss supplement, contains unlisted and active drug ingredients.

Que She is advertised as "Slimming Factor Capsule" and "an all-natural blend of Chinese herbs." It has been widely distributec on Internet sites and at retail outlets.

The risk: The drug ingredients may harm consumers, especially those with conditions that affect the heart and blood vessels (cardiovascular conditions). These ingredients also may interact with other medications and result in serious side effects.

FDA analysis of Que She found that it contains the following ingredients:

- fenfluramine—a stimulant withdrawn from the U.S. market in 1997 after studies demonstrated that it caused serious heart valve damage
- propranolol—a prescription beta blocker that can pose a risk to people with bronchial asthma and certain heart conditions
- sibutramine—a controlled substance and prescription weight-loss drug; preliminary study results showed an association between sibutramine use and increased risk of heart attack and stroke in people who have a history of heart disease
- ephedrine—a stimulant drug that is legally marketed over-the-counter for temporary relief of asthma but can pose a ris to people with certain cardiovascular conditions.

Recommendation: Stop taking Que She immediately, and contact your health care professional.

For More Information

FDA News Release[13]

Chinese Version of FDA News Release[14]

back to top

Recall: Unapproved Drugs Sold as Dietary Supplements

FDA has warned consumers not to use several unapproved drug products that are being marketed as dietary supplements. Each product contains an active ingredient of an FDA-approved prescription drug. The active ingredient is not listed on the product label.

The risk: The active drug ingredients could harm consumers, especially those with certain health conditions. The active ingredients may also interact with other medications being taken and result in serious side effects. See the table below for more information.

Product Name	Active Drug Ingredient	Risk	Identifying Information	For More Information
ejaculoid XXTREME and stimuloid II	Chemical compounds similar to sildenafil, found in a prescription erectile dysfunction drug	May interact with prescription drugs such as nitroglycerin; may lower blood pressure to dangerous levels	See product photos[15] ejaculoid XXTREME sold 30 capsules per bottle; recalled lot code is 79935 12/12 stimuloid II sold 30 capsules per bottle; recalled lot code is 79936	Call Nutraloid Labs Inc. at 772-291-7510
Vialipro	Chemical compounds similar to sildenafil, found in a prescription erectile dysfunction drug	May interact with prescription drugs such as nitroglycerin; may lower blood pressure to dangerous levels	Sold 10 capsules per bottle; recalled lot codes are 80409, 80661, 81146, 90132, 90265, 90587, 90826, 91065	Call Good Health Inc. at 866-607-0338
Joyful Slim Herb Supplement	desmethyl sibutramine, found in a prescription weight-loss drug	May increase blood pressure or pulse rate and harm people with a history of heart disease or stroke	Sold 30 capsules per bottle; recalled lot code is 101408	Call J & H Besta Corp. at 877-547-5468 or 516-735-1436
Slim-30 Herb Supplement	N-desmethyl sibutramine and traces of sibutramine, found in a prescription weight-loss drug	May increase blood pressure or pulse rate and harm people with a history of heart disease or stroke	Sold 30 capsules per bottle; recalled lot code is 032009	Call J & H Besta Corp. at 877-547-5468 or 516-735-1436

Recommendations

- Stop using these products immediately.

- Contact your health care professional if you have experienced any problems that may be related to taking these products.

For More Information

Nutraloid Labs Press Release on Ejaculoid XXTREME and Stimuloid II[16]

Good Health Inc. Press Release on Vialipro[17]

J & H Besta Corp. Press Release on Joyful Slim[18]

J & H Besta Corp. Press Release on Slim-30[19]

This article appears on FDA's Consumer Updates page[20], which features the latest on all FDA-regulated products.

Posted August 20, 2010

back to top

For More Information

- 2010 Safety Alerts for Human Medical Products[21] [ARCHIVED]
- FDA's MedWatch Safety Alerts: June 2010[22] [ARCHIVED]
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program[23]

Links on this page:

1. /Safety/MedWatch/default.htm
2. http://service.govdelivery.com/service/subscribe.html?code=USFDA_9
3. /AboutFDA/ContactFDA/StayInformed/RSSFeeds/Consumers/rss.xml
4. http://www.fda.gov/Safety/MedWatch/default.htm
5. https://www.accessdata.fda.gov/scripts/medwatch/
6. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm220217.htm
7. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm
8. http://www.fda.gov/ICECI/CriminalInvestigations/default.htm
9. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm217879.htm
10. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm217599.htm
11. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm218202.htm
12. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm218679.htm
13. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm218427.htm
14. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm218428.htm
15. http://www.fda.gov/Safety/Recalls/ucm220602.htm
16. http://www.fda.gov/Safety/Recalls/ucm220601.htm
17. http://www.fda.gov/Safety/Recalls/ucm219558.htm
18. http://www.fda.gov/Safety/Recalls/ucm219962.htm
19. http://www.fda.gov/Safety/Recalls/ucm219449.htm

20. http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm
21. /Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm196258.htm
22. /ForConsumers/ConsumerUpdates/ucm217775.htm
23. /Safety/MedWatch/default.htm